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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/204,236	12/03/1998	GREGORY S. HAMILTON	AR218-X	5251
29728	7590	10/24/2006		
GUILFORD PHARMACEUTICALS C/O FOLEY & LARDNER LLP 3000 K STREET, NW WASHINGTON, DC 20007-5143				
			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/204,236

Applicant(s)

HAMILTON ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 90,92-99 and 101-111 is/are pending in the application.
- 4a) Of the above claim(s) 97,98,106 and 107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 90, 92--96, 99, 101-105, 108-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Amendment and response filed by applicants dated Aug. 27, 2006 have been entered and considered carefully.

Claims 1-89, 91, 100 have been canceled. Claims 97-98, 106-107 stayed withdrawn from consideration. Claims 90, 92-96, 99, 101-105, 108-111 are pending.

2. The rejection of claims 90, 92-96, 99, 101-105, 108-111 under 35 USC 112 first paragraph is maintained for reason of record.

Applicants argued that based on description and data of tables II and III, the claimed compounds were indicated to have in vivo activity in neuronal regeneration activity in mice. Please note that the claims are drawn to “method of treating a neurological disorder” which is not commensurate with the description and enabling support of the specification based on description of p. 22 and table II-III, that the compounds have activity to stimulate neuronal regeneration and growth in a mammal. Please note that treating “neurological disorder” must treat the disease while neuronal regeneration can provide the mammal with certain functional compensation resulted from loss of neuron, does not necessarily treat what is causing the disease or disorder (see p.38-39 increasing density of dopaminergic neurons only). It is recommended that the scope of the claims be commensurate with the description and enablement of the specification i.e. “a method of stimulating neuronal regeneration and growth in a mammal” having peripheral neuropathies caused by physical injury.....etc. comprising administering a therapeutically effective amount of a compound of formula I.

3. Claims 90 and 99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description as well as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention; and the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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In the specification on page 15, description of various salts of the compounds without any description of which compounds will form what solvates or with which solvents a solvate can form. The specification contains none of the compound, which is a solvate. While a pharmaceutical addition salt can be prepared routinely upon in possession of an acid or basic compound, the solvate formation is the innate nature of a compound upon contacting a certain solvent. Without any description of what solvent will form solvate with which compound and completely silent of the existence of any solvate or hydrate, the specification offered mere language rather than possession or enablement of the solvates.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Oct. 18, 2006



Celia Chang  
Primary Examiner  
Art Unit 1625